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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/562,585

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Markus Hahl

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COHEN, PONTANI, LIEBERMAN & PAVANE
551 FIFTH AVENUE
SUITE 1210
NEW YORK, NY 10176

EXAMINER

FERNANDEZ, KATHERINE L

ART UNIT

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3768

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ED

Office Action Summary	Application No. 10/562,585	Applicant(s) HAHL, MARKUS	
	Examiner Katherine L. Fernandez	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 December 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/28/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

2. The information disclosure statement filed on December 28, 2005 is acknowledged. The information disclosure statement meets the requirements of 37 C.F.R. 1.97 and 1.98 and therefore the references therein have been considered.

Drawings

3. The drawings are objected to because Figures 1-2 and 4-5 are missing from the application. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

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the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 39-44, 49-54, and 65 are rejected under 35 U.S.C. 102(b) as being anticipated by Gershteyn et al. (US Patent No. 6,348,694).

With regards to claims 39, Gershteyn et al. disclose methods and apparatus for determining both an ability of the skin to withstand exposure to the harmful radiation, such as ultraviolet radiation, as well as safe exposure time of the skin to the harmful radiation (abstract; column 1, lines 8-12). Their device comprises of a UV emitter (100, column 7, lines 1-49, column 19, lines 9-46) for emitting UV radiation on the skin, a UV sensor (70) for receiving UV radiation diffusely reflected by the skin, and an evaluation unit (80, 82, 84, and 86) coupled to the UV emitter and the UV sensor for determining UV radiation absorption of the skin based on the UV radiation emitted on the skin by the UV emitter and the UV radiation received by the UV sensor (column 20, line 42 through column 21, line 29). See Figures 5-7.

With regards to claims 40-42, Gershteyn et al. disclose that any wavelength range within the absorption spectrum of sunscreen can be selected for use as the radiation wavelength (column 11, lines 46-52). Further, they disclose that most

absorbing sunscreens are typically designed to have an absorption spectrum below approximately 400 nm (column 11, lines 27-29). In this range, the UV emitter can emit UV radiation for which the skin has an absorption coefficient greater than or equal to a scattering coefficient, having a wavelength smaller than the diameter of a skin cell nucleus, and having a wavelength of approximately 345 nm to 355 nm would fall within this range.

With regards to claim 43, as can be seen from Figures 5-6, the UV emitter and the UV sensor are disposed in a housing of a hand-held instrument (90) (column 21, lines 30-38).

With regards to claim 44, the housing (90) has an application surface (22) for placement on the skin (24) (Figure 6). Further, Gershteyn et al. disclose that optical guides, such as fibers, planar waveguides, or waveguides having various other geometries may be selected as suitable radiation paths for their invention (column 11, lines 4-16). Further, they disclose that the radiation sensors having planes of incidence at various orientations are employed to detect ambient radiation at a number of incidence angles (column 19, lines 18-28). The sensors can be arranged such that radiation from several directions may be detected from various locations proximate (i.e. 1 nm below the application surface) to the skin (column 19, lines 18-46).

With regards to claims 49-51 and 65, Gershteyn et al. disclose that their apparatus includes a processor unit (86) that is coupled to the evaluation unit (80, 82, 84). They disclose that the processor may calculate a sum of the signals representing the total exposure level of the skin to the radiation, as well as calculate and provide information

relating to the directionality of radiation impinging on the apparatus (column 20, line 42 through column 21, line 30). A peak exposure signal can be passed to the processor (column 21, lines 6-17). The processor may also include various memories (RAM,ROM) (column 21, lines 18-29).

With regards to claims 52-53, Gershtyn et al. disclose that their apparatus comprises an interface (86, 102, processor with a central processing unit and memory; user-interface) for storing and retrieving data (Figure 7, column 21, lines 39-48). Further, they disclose that the interface can be used to operate a UV radiation source (i.e pressing the "START" button on the user interface) (column 21, lines 30-38; column 22, lines 14-27).

With regards to claim 54, as can be seen from Figures 5-6, the housing (90) has two pairs of UV sensors (70A, 70B, 70C, and 70D), with the two UV sensors in each pair oppositely disposed, and the two pairs of UV sensors are disposed at an angle of approximately 90 degrees relative to each other (Figures 5-6).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 45-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gershteyn et al.

With regards to claims 45-48, Gershteyn et al. disclose that the sensors can be arranged so that radiation can be detected from several directions from various locations (i.e. depth of penetration can be varied) (column 19, lines 18-46). As stated above, they also disclose that the radiation sensors can have planes of incidence at various orientations to detect ambient radiation at a number of incidence angles (i.e. angle of the optical axes can be adjusted to vary the depth of penetration) (column 19, lines 18-28). The radiation sensors may be spaced apart, or distributed partially or fully around the apparatus in a variety of positional arrangements (i.e. the distance above the application surface can be adjusted to vary the depth of penetration)(column 19, lines 18-22). However, they do not specifically disclose that the optical axes of the UV emitter and the UV sensor span an angle of approximately 70-110 degrees. At the time of the invention, it would have been obvious to one of ordinary skill in the art to have the optical axes of the UV emitter and the UV sensor span an angle of 70-110 degrees. The motivation for doing so would have been that Gershteyn et al. disclose that the radiation sensors can have planes of incidence at various orientations to detect radiation at a number of incidence angles (which can include an angle of 70-110 degrees) in order to achieve accurate measurements of the total exposure level of the skin to ultraviolet radiation (column 6, lines 47-67; column 19, lines 18-28).

8. Claims 55-59 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gershteyn et al. in view of Benaron et al. (US Patent No. 5,807,261)

Gershteyn et al. disclose that the sensors can detect ultraviolet radiation (i.e. erythema-effective spectrum) (column 11, lines 40-60). With regards to claim 64,

Gershtyn et al. disclose that their apparatus comprises an interface (86, 102, processor with a central processing unit and memory; user-interface) for storing and retrieving data (i.e. databank for storing data received by the sensor) (Figure 7, column 21, lines 39-48). However, they do not specifically disclose that their device further comprises four optical waveguides, each of the optical waveguides having a free end, and the two pairs of UV sensors are formed by the free ends of the optical waveguides. They also do not disclose that the free ends of the optical waveguides has a filter operable to cause a short-wave component of a diffusely reflected UV radiation to be reflected to a greater extent than a long-wave component of the diffusedly reflected UV radiation, nor that each of the optical waveguides is connected to a common UV sensor. Benaron et al. disclose sensors for in vivo measurements of body tissues (column 1, lines 25-29). They disclose an embodiment of their invention that provides a tissue interrogating tool including a penetrating device with an optical sensor for use in determining whether or not the penetrating device has penetrated to the desired body cavity (column 20, lines 28-41). They disclose that the optical sensor may have a multiplicity of optical components at the distal end of the puncturing tool for emitting and launching light and coupling and detecting light to provide a signal corresponding to the spectral characteristics of the tissue presented to the tool (column 20, lines 33-41). The light detecting window may be one optical waveguide adapted to receive all light sensed, or alternately, the light detecting window may have separate optical waveguides for receiving the light (i.e. sensors comprised of optical waveguides) (column 21, lines 12-26). Further, they disclose that the sensed light signals are can be demultiplexed by

time using frequency selective filters that will chop the sensed light into frequency selective signals. At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the device of Gershteyn et al. to include the limitations listed above. The motivation for doing so would have been to receive all light sensed and to chop the sensed light into frequency selective segments in order to acquire the desired spectral characteristics, as taught by Benaron et al. (column 21, lines 12-26, column 26, lines 57-67).

9. Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gershteyn et al. in view of Lenderink et al. (US Patent No. 6,736,832).

Gershteyn et al. do not specifically disclose that the distance between the two UV sensors of one pair of the two pairs of UV sensors is approximately equal to a height of a human body lying on a tanning bed. Lenderink et al. disclose a method comprising the steps of determining a quantity related to a person's personal minimum erythema dose and using the quantity as an input for a tanning-related device, influencing its operation (column 1, lines 8-13). They disclose that the tanning is induced by irradiation with ultraviolet light (column 1, lines 14-15). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have the UV sensors be approximately equal to a height of a human body lying on a tanning bed. The motivation for doing so would have been that the device could be used in connection with a tanning device and having the sensors equal to a height of a human body lying on a tanning bed would allow the person to determine when they have been exposed to the radiation for

too long and thus avoid radiation damage, as taught by Lenderink et al. (column 1, lines 14-60).

10. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gershteyn et al. in view of Lipman et al. (US Pub. No. 2002/0052562).

Gershteyn et al. do not disclose that their device further comprises a distance measuring instrument for maintaining a predetermined distance between a UV radiation source and skin. Lipman et al. discloses neurological diagnostic tools including method and devices for monitoring and managing patient pain (pg. 1, paragraph [0002]). They disclose one embodiment of their system that includes a hand held fixture to hold a heat source assembly that includes two projector bulbs to generate the heat beam (pg. 8, paragraph [0086]). Also included in their invention is a distance measuring device (pg. 8, paragraph [0086]). The device provides a display indicator to tell the operator how to adjust the hand held unit (i.e. toward or away from the skin) in order to keep it at the proper distance (pg. 8, paragraph [0086]). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have included a distance measuring instrument in the invention of Gershteyn et al. The motivation for doing so would have been in order to tell the operator how to adjust the device in order to keep it at the proper distance, as taught by Lipman et al. (pg. 8, paragraph [0086]).

11. Claims 62-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gershteyn et al. in view of Shi (US Patent No. 5,107,123).

Gershteyn et al. do not disclose that their device further comprises a temperature sensor. Further, they do not disclose that the temperature sensor is coupled to an

evaluation unit and is operable to initiate a UV radiation absorption determination of the skin when an optimum bulb wall temperature of a UV radiation source to be measured in a tanning bed is reached. Shi discloses an ultraviolet radiation measuring device for measuring ultraviolet radiation in a selected environment. They disclose that their invention includes a temperature sensor located in close proximity with an optical-electrical signal converter (column 6, lines 62-63). The temperature sensor monitors the ambient temperature and provides electrical signals indicative of the monitored temperature (column 6, lines 62-66). The temperature is displayed and used for further processing of the UV intensity signal (column 6, line 62 through column 7, line 4). A processor takes a digital ultraviolet intensity signal and digital temperature signal and generated display signals representative of the instantaneous radiation levels present in the area sensed by the device (i.e. temperature sensor is coupled to a processor, which serves as an evaluation unit)(column 7, lines 26-32). The processor also integrates the measured levels over time to calculate an accumulated ultraviolet radiation value used to obtain a prescribed radiation dose (column 7, lines 32-36). At the time of the invention, it would have been obvious to one of ordinary skill in the to have included the limitations discussed above. The motivation for doing so would have been to generate an ultraviolet intensity signal which is independent of ambient temperature, as taught by Shi (column 5, lines 56-65).

12. Claim 66 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gershtyn et al. in view of Wulf (US Patent No. 4,882,598).

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Gershtyn et al. do not disclose that when the maximum UV exposure time or UV radiation is reached, the UV radiation source is shut off. Wulf et al. disclose a method and an apparatus for determining an individual's ability to stand exposure to ultraviolet radiation prior to causing a skin reaction, or for determining an individual's ability to become tanned by exposure to ultraviolet radiation (abstract). They disclose that their invention determines when an individual should not expose his or her body to ultraviolet radiation (i.e. when maximum UV exposure time or UV radiation is reached) and if the computer has determined that the individual is erythrodermic or erythematous, the power to the tubes or bulbs are cut off (i.e. radiation source is shut off) (column 18, line 41 through column 19, line 16).

13. Claims 67-68 and 75-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wulf.

With regards to claim 67 and 75, Wulf discloses a method of determining an allowable UV exposure time or allowable UV radiation dose for human skin (column 1, lines 54-66). Their method comprises determining absorption of erythemally-effective UV radiation in a layer of skin (column 4, lines 34-64). A UV radiation threshold values is assigned to the determination of UV radiation absorption of the skin of a human being (column 2, lines 12-38). However, they do not specifically disclose that the skin has developed hyperkeratosis. Wulf does disclose that their invention can be applied to people who are erythrodermic or erythematous, suggesting that their invention can be applied to individuals with hyperkeratosis (i.e. skin disorder/sensitive skin) (column 3, line 58 through column 4, line 28). At the time of the invention, it would have been

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obvious to one of ordinary skill in the art to have applied the invention of Wulf to skin that has developed hyperkeratosis. The motivation for doing so would have been that Wulf disclose that their invention can be applied to individuals who are erythrodermic or erythematous (i.e. skin disorders), as taught by Wulf (column 3, line 58 through column 4, line 28).

With regards to claim 68, Wulf discloses that the UV radiation can be carried out by means of direct UV irradiation (column 6, lines 48-60).

With regards to claim 76, Wulf discloses that their method is carried out by using a device comprising a UV emitter (40) for emitting UV radiation on the skin, a UV sensor (44) for receiving UV radiation diffusely reflected by the skin, and an evaluation unit (30) coupled to the UV emitter and UV sensor for determining UV radiation absorption of the skin based on the UV radiation emitted on the skin by the UV emitter and the UV radiation received by the UV sensor (column 11, line 11 through column 12, line 8; column 6, lines 48-60).

14. Claim 69 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wulf in view of Anderson et al. (US Pub. No. 2003/0045916).

Wulf does not disclose that the UV radiation is carried out by means of fluorescence photometry. Anderson et al. disclose an invention relating to the treatment of psoriasis and other proliferative skin disorders using phototherapeutic techniques. They disclose that UV radiation is carried out by means of fluorescence photometry (pg. 6, paragraph [0060]). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have the UV radiation carried out by means of fluorescence

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photometry. The motivation for doing so would have been ultraviolet phototherapy to treat skin disorders, as taught by Anderson et al. (pg. 1, paragraphs [0005] – [0006]).

15. Claim 70 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wulf in view of Kaminski et al. (US Patent No. 5,640,957).

Wulf does not specifically disclose that a mean value of a plurality of determinations of UV radiation absorption of the skin is taken, and a UV radiation threshold value is assigned to the mean value. Kaminski et al. disclose an apparatus for evaluating the effectiveness and determining the appropriate sun protection factor (SPF) rating of sunscreens (column 1, lines 8-12). They disclose that their method includes computing the average sun protection factor for the desired range (i.e. UVA or UVB) or the combined entire ultraviolet range (column 4, lines 49-58). At the time of the invention, it would have been obvious to one of ordinary skill in the art to calculate a mean value of a plurality of determinations of UV radiation absorption of the skin, and assign a UV radiation threshold value to the mean value. The motivation for doing so would have been to provide a reliable indicator, as taught by Kaminski et al. (column 5, lines 2-6).

16. Claims 71-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wulf in view of Kaminski et al. as applied to claim 70 above, and further in view of Gershteyn et al..

Wulf in view of Kaminski et al. do not specifically disclose that the determinations are made at different sites of the skin nor at different depths of the skin. Gershteyn et al. disclose that sensors can be arranged such that radiation from several directions

may be detected from various locations (i.e. different sites and different depths) proximate to the skin (column 19, lines 18-46). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have the determinations made at different sites of the skin and at different depths of the skin. The motivation for doing so would have been to be able to provide an accurate measurement of the radiation that actually irradiates the skin, as taught by Gershteyn et al. (column 19, lines 29-46).

17. Claims 73-74 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wulf in view of Gershteyn et al.

With regards to claim 73-74, Wulf does not disclose that a maximum UV exposure time or UV radiation dose is determined from the threshold value and stored data of a UV radiation source, nor does he disclose that the stored data are data derived from a measurement of the UV radiation source. Gershteyn et al. disclose that their apparatus comprises includes a processor with a central processing unit and memory for storing and retrieving data (Figure 7, column 21, lines 39-48). Further, they disclose that their apparatus may store an initial calculation (i.e. data derived from a measurement of the UV radiation source) in memory so that the calculation may be compared to the calculation measured at later times (column 21, lines 39-48). Further, they disclose that their apparatus can provide a measure of cumulative tan (column 21, lines 49-61). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have the maximum UV exposure time or UV radiation dose determined from the threshold value and stored data of a UV radiation source. The motivation for

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doing so would have been that stored data can provide a cumulative calculation, as taught by Gershtyn et al. (column 21, lines 30-61).

With regards to claim 76, Gershteyn et al. disclose methods and apparatus for determining both an ability of the skin to withstand exposure to the harmful radiation, such as ultraviolet radiation, as well as safe exposure time of the skin to the harmful radiation (abstract; column 1, lines 8-12). Their device comprises of a UV emitter (100, column 7, lines 1-49, column 19, lines 9-46) for emitting UV radiation on the skin, a UV sensor (70) for receiving UV radiation diffusely reflected by the skin, and an evaluation unit (80, 82, 84, and 86) coupled to the UV emitter and the UV sensor for determining UV radiation absorption of the skin based on the UV radiation emitted on the skin by the UV emitter and the UV radiation received by the UV sensor (column 20, line 42 through column 21, line 29). See Figures 5-7. At the time of the invention, it would have been obvious to one of ordinary skill in the art to have the method of Wulf carried out by this device. The motivation for doing so would have been . The motivation for doing so would have been to be able to non-invasively determine an ability of a region of skin to withstand exposure to harmful radiation, as taught by Gershteyn et al. (abstract).

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine L. Fernandez whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni M. Mantis-Mercader can be reached on (571)272-4740. The fax

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phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


ELENI MANTIS MERCADER
SUPERVISORY PATENT EXAMINER